NOV 21 2002

K023585

10.0 SUMMARY OF SAFETY AND EFFECTIVENESS

Manufacturer:	IntraVascular Incorporated 3600 Bur Wood Drive Waukegan, Illinois 60085
Contact:	Steve Aperavich President, IntraVascular Incorporated
Telephone Number: Fax Number:	847-596-7700 847-596-7710
Date Summary Prepared:	November 18, 2002
Product Trade Name:	FLOSTAR Needleless Connector
Common Name:	Needle-less I.V. Access Valve Classification: Set, Administration, Intravascular 21 CFR 880.5440
Predicate Devices:	Safe-Connect Valve

Description:

The FLOSTAR Needleless Connector is a sterile, disposable, needle-less I.V. access valve for use in general intravenous administration of fluids.

Intended Uses/Indications:

The FLOSTAR Needleless Connector device is sterile, disposable, needle-less I.V. access valve for use in intravenous administration of fluids to a patient's vascular system. The FLOSTAR Needleless Connector device may aid in the prevention of needle stick injuries.

Substantial Equivalence:

The FLOSTAR Needleless Connector is substantially equivalent to the current Safe-Connect Valve in that:

- have the same intended use,
- use the same operating principle,
- incorporate the same final design configuration
- are both labeled as single patient use
- are packaged and labeled using the same materials and processes

Summary of Testing:

All materials used in the fabrication of this FLOSTAR Needleless Connector were evaluated with the original design through physical testing and biocompatibility testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2002

Mr. Steve Aperavich
President
IntraVascular Incorporated
3600 Bur Wood Drive
Waukegan, Illinois 60085

Re: K023585
Trade/Device Name: FLOSTAR Needleless Connector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 22, 2002
Received: October 25, 2002

Dear Mr. Aperavich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K023585

510(k) Number (if known): K023585

Device Name: FLOSTAR Needleless Connector

Indications For Use:

The FLOSTAR Needleless Connector device is sterile, disposable, needle-less I.V. access valve for use in intravenous administration of fluids to a patient's vascular system. The FLOSTAR Needleless Connector device may aid in the prevention of needle stick injuries.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** _____ **Over -The-Counter Use**
(Per 21 CFR 801.109)

Patricia Cascuito
(Division Sign-Off)
Division of Dental, Infection Control,
And General Hospital Devices

5109(k) Number K023585